REMARKS

Claims 1-11 and 30-32 will be pending upon entry of this Amendment and Response After RCE. Claims 1 and 7 have been amended to require the method for decreasing the appetite of an obese or overweight mammal to include enterally administering an amount of long chain n-3 polyunsaturated fatty acid at a time prior to or in conjunction with an appetite-impacting stimulus. Support for these amendments can be found in dependent claims 4 and 9, and further, in the instant specification on page 18, lines 18-30. Upon entry of this Amendment and Response After RCE, Applicants respectfully request reconsideration and allowance of all pending claims.

1. Rejection of the claims under 35 U.S.C. §112, First Paragraph

Reconsideration is requested of the rejection of claims 1-11 and 30-32 under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. Specifically, the Office states that the specification and claims as originally filed fail to provide adequate written description for the limitation directed to the step of identifying said overweight or obese mammal to be treated.

Applicants respectfully disagree as support for this step of the method can be found in the instant specification on page 1, lines 3-6 and page 2, lines 17-21, in which it is specifically noted that the instant methods are directed to treating obesity and conditions of overweight mammals,

especially the pediatric population. As defined by Merriam-Webster, to "treat" refers to caring for or dealing with medically or surgically, such as to treat a disease.[1] Accordingly, in order to care for or deal with a condition such as obesity and conditions of overweight, the obesity and conditions of overweight must be identified.

Furthermore, suitable means for identifying an obese or overweight mammal are adequately described in the specification (particularly, on page 2, lines 14-22), in which overweight is defined as having a BMI of between 25 and 29.9, and obesity is defined as a BMI of greater than 30.

Based on the foregoing, the limitation of claims 1-11 and 30-32 are adequately described by the instant specification and accordingly, this rejection should be withdrawn.

2. Rejection of the Claims under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 1-4, 6, and 30-32 under 35 U.S.C. §103(a) as being unpatentable over Phinney, et al. (WO 03/043570) in view of Visser, et al. ("Elevated C-Reactive Protein Levels in Overweight and Obese Adults", Journal of the American Medical Association, 1999; 282:2131-215).

Claim 1, as amended herein, is directed to a method for decreasing the appetite of an obese or overweight mammal comprising: identifying an obese or overweight mammal; and enterally administering at a time prior to or in conjunction

[1] *See* Merriam-Webster's on-line dictionary, available at http://www.merriam-webster.com/dictionary/treat.

with an appetite-impacting stimulus to said mammal an amount of long-chain n-3 polyunsaturated fatty acid effective to decrease the appetite of said mammal, wherein the polyunsaturated fatty acid has 20 or more carbon atoms, and wherein the polyunsaturated fatty acid is administered in the form of a triacylglycerol to treat obesity or overweight in mammals that are obese or overweight.

Phinney, et al. disclose formulations and methods for the treatment and/or amelioration of symptoms of inflammatory conditions and associated systemic inflammatory responses. Phinney, et al. disclose that elevated levels of C-reactive protein have been associated with these various inflammatory conditions. The compositions comprise a non-alpha tocopherol (especially gamma-, beta-, or delta-tocopherol) and one or more of an omega-3 fatty acid, such as docosahexaenoic acid (DHA) or a flavonoid.

Significantly, Phinney, et al. fail to disclose a method of enterally administering at a time prior to or in conjunction with an appetite-impacting stimulus to said mammal an amount of long-chain n-3 polyunsaturated fatty acid effective to decrease the appetite of said mammal. This is a requirement of Applicants' claim 1. More particularly, **no where is there any mention of an appetite-impacting stimulus** in the Phinney, et al. reference. As defined in the instant Specification, an "appetite-impacting stimulus" is any stressor or stimulus that has the effect of increasing food intake (i.e., eliciting an appetitive response). Examples provided include irregular

meals, sleep deprivation, and the like.[2] Particularly, it is beneficial to administer the long-chain n-3 polyunsaturated fatty acid prior to or in conjunction with the stimulus so as to decrease the appetite of an obese or overweight mammal at the time or prior to the stimulus, which has the effect of increasing food intake; that is, the long-chain n-3 polyunsaturated fatty acid is to be administered at the time or prior to when it is most effective.

Recognizing that the Phinney, et al. reference fails to teach or suggest each and every limitation of Applicants' claimed invention, the Office cites the Visser, et al. reference for combination with Phinney, et al. Specifically, Visser, et al. is cited for its disclosure of using the guideline parameter of body mass index to identify patients that are overweight or obese and have the C-reactive protein biomarker.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2142 requires a clear articulation of the reasons why the claimed invention would have been obvious. Specifically, the Supreme Court in KSR International Co. v. Teleflex Inc., 127 S.Ct. 1727, 82 USPQ2d 1385, 1396 (2007) noted that the burden lies initially with the Office to provide an explicit analysis supporting a rejection under 35 U.S.C. 103. "[R]ejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some **articulated reasoning** with some **rational underpinning** to support the legal conclusion of obviousness." The Court in KSR International further identified a number of rationales to support a

[2] Specification at page 18, lines 18-30.

conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in Graham v. John Deere Co. (383 U.S. 1, 148 USPQ 459 (1966). Specifically, as previously required by the TSM (teaching, suggestion, motivation) approach to obviousness, one exemplary rationale indicated requires some teaching, suggestion, or motivation in the prior art references that would have led one of ordinary skill to modify/combine the prior art references to arrive at the claimed invention. Specifically, to reject a claim based on this rationale, the Office must articulate the following: (1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings to arrive at each and every limitation of the claimed invention; (2) a finding that there was reasonable expectation of success; and (3) whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness. The Office has failed to meet its burden under number (1) above, as the combined reference teachings fail to teach or suggest each and every limitation of claim 1, and further, there is no apparent reason for one skilled in the art to combine the reference teachings to arrive at each and every limitation. It simply would not have been obvious to one skilled in the art to arrive at Applicants' claimed combinations.

Specifically, as noted above, no where in the cited references (or in the knowledge available to one skilled in the art) is there an apparent reason to combine or modify the references to arrive at the claimed limitation of enterally administering **at the time prior to or in conjunction with an appetite-impacting stimulus** to an obese or overweight mammal an amount of long-chain n-3 polyunsaturated fatty acid effective to **decrease the appetite of said mammal and treat the obesity or conditions of overweight**. At best, Visser, et al. disclose that individuals who are obese and/or overweight, as defined using the BMI scale were slightly more likely to have elevated CRP levels,[3] and further, Visser, et al. and Phinney, et al. recognize that elevated CRP levels are related to systemic inflammatory conditions and associated disorders. Further, Phinney, et al. teach administering a composition comprising non-alpha tocopherol and one or more of an omega-3 fatty acid or flavonoid to treat or ameliorate the various inflammatory conditions. No where, however, is there any suggestion that the composition of Phinney, et al. should be administered at the time prior to or in conjunction with an appetite-impacting stimulus, which as noted above can increase feed intake by the individual, to decrease appetite such to treat obesity and/or conditions of overweight. This is a requirement of Applicants' claimed invention.

Moreover, no where is it even mentioned that the composition of Phinney, et al. can be used to decrease appetite.

[3] As taught on page 2133 of Visser, et al., obese men were 2.13 times more likely and obese women 6.21 times more likely to have elevated CRP levels compared with their normal-weight counterparts.

Although there is potential overlap between the specific diseases (that of having elevated C-reactive protein levels) there is nothing in the references (alone, or in combination), to teach or suggest that administering the composition of Phinney, et al. will effect the treatment of obesity or overweight, which is identified in Visser, et al. This is especially true in the cases of overweight individuals who are otherwise healthy and not suffering from elevated C-reactive protein levels. As such, why would one skilled in the art modify the method of Phinney, et al. to identify an obese or overweight individual and administer the tocopherol composition at the time prior to or in conjunction with an appetite-impacting stimulus to decrease appetite as required in the method of Applicants' claim 1? There is simply no apparent reason to do so.

Accordingly, there is no articulated reason to combine the teachings of the cited references to arrive at each and every limitation of Applicants' claim 1. As such, claim 1 cannot be said to be obvious in view of the cited references.

As claims 2-4, 6, and 30-32 depend directly or indirectly from claim 1, claims 2-4, 6, and 30-32 are patentable for the same reasons as claim 1.

3. Rejection of the Claims under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 7-9 and 11 under 35 U.S.C. §103(a) as being unpatentable over Phinney, et al. in view of Visser, et al. and Bogentoft (WO

87/03198) in further view of The Merck Index (Monograph 5383, page 867).

Claim 7, as amended herein, is similar to claim 1 discussed above, and further requires administering an amount of long-chain n-3 polyunsaturated fatty acid and an amount of long-chain n-6 polyunsaturated fatty acid prior to or in conjunction with an appetite-impacting stimulus to decrease the appetite and treat obesity or overweight in obese or overweight mammals.

As discussed above, neither Phinney, et al. nor Visser, et al., alone or in combination, teach or suggest each and every limitation of the claimed invention, and further, there is no apparent reason for combining the reference teachings. Bogentoft and the Merck Index fail to overcome these shortcomings. Particularly, there is simply no reason to combine the references to arrive at each and every limitation of claim 7.

Bogentoft discloses enteric preparations in the forms of capsules, tablets, and microcapsules having an enteric coating resistant to gastric juices that dissolves only in the ileum. These enteric preparations contain a hydrophobic substance in combination with an emulsifier. The hydrophobic substance is thus delivered to the ileum, at which point it interacts with specific ileum receptors to induce satiety (page 1, paragraph 3). The enteric preparation is orally administered in a weight reducing dosage to a human. The hydrophobic substance can be a fatty acid having 6-28 carbon atoms, an ester or a salt thereof, a fatty alcohol having 6-28 carbon atoms or an ester thereof.

The Merck Index discloses the formula and properties for linolenic acid. Specifically, The Merck Index discloses that linolenic acid is the same compound as alpha-linolenic acid.

Similar to Phinney, et al. and Visser, et al. discussed above, Bogentoft and The Merck Index fail to teach or suggest administering a composition with the long-chain n-3 polyunsaturated fatty acid and long-chain n-6 polyunsaturated fatty acid prior to or in conjunction with an appetite-impacting stimulus. At best, Bogentoft teach administering their composition 2-5 hours prior to meal time such that the composition has time to interact with specific ileum receptors to induce satiety to decrease appetite. No where, however, is it taught or suggested that the composition could be administered prior to a stressor or stimuli that can lead to increased food intake (i.e., appetite-impacting stimulus), such as sleep deprivation and irregular meal times, such as disclosed in Applicants' specification and claimed in claim 7. The composition of Bogentoft is designed to be used in a completely different manner to treat obesity and conditions of overweight.

Moreover, as noted by the Office on page 14 of the Final Office action, Phinney, et al. teach their composition to have efficacy in reducing elevated levels of C-reactive protein in patients that suffer from such elevated levels; and a proportion of these patients also suffer from concomitant obesity or overweight status. As **only** a portion of the patients treated in Phinney, et al. are obese or overweight, there is no reason to select the composition of Bogentoft, which is solely disclosed for treating obesity and overweight, for combination with the

composition of Phinney, et al. that is also directed for use to patients that are not obese or overweight. With all due respect, it appears that the Office has merely used hindsight reasoning in combining these references, which has been specifically instructed against by the Federal Circuit.

As further discussed in the Amendment and Response to Office Action submitted December 20, 2007, while Bogentoft state that its hydrophobic substance can be a fatty acid having 6-28 carbon atoms, Bogentoft actually only disclose and enable fatty acids having up to 18 carbon atoms. The fatty acid can be saturated or unsaturated, and have a branched or a straight chain. The fatty acids include lauric acid, palmitic acid, stearic acid, oleic acid, ricinoleic acid, linoleic acid, and linolenic acid. Accordingly, Bogentoft fails to disclose administering an amount of long chain n-3 polyunsaturated fatty acid, wherein the long chain n-3 polyunsaturated fatty acid has 20 or more carbon atoms, effective in decreasing the appetite of an obese or overweight mammal. Specifically, as described in the instant specification, and as required in amended claim 7, "long chain n-3 polyunsaturated fatty acid" refers to fatty acids having 20 or more carbons and having a double bond at the third carbon (*see* Specification at page 16, line 29 through page 17, line 7). Furthermore, the only omega-3 fatty acids listed as suitable for the composition of Phinney, et al. include long chain n-3 polyunsaturated fatty acids such as docosahexaenoic acid, having 22 carbons, and eicosapentaenoic acid, having 20 carbons.

As no where it is taught or suggested in Bogentoft to administer a long chain n-3 polyunsaturated fatty acid having 20 or more carbon atoms as its hydrophobic substance to be used in the enteric preparation administered for weight loss, Applicants respectfully assert that there is simply no reason for combining the composition of Bogentoft with that of Phinney, et al. More particularly, why would one skilled in the art combine the compositions of Bogentoft and Phinney, et al., when each provides ample examples of fatty acids for use in their respective compositions, particularly, when the composition of Phinney, et al. already provides satisfactory fatty acids, all of which have 20 or more carbon atoms, for treating elevated CRP levels (which may or may not include individuals that are obese or overweight). There simply is no apparent reason to do so.

As the cited references fail to provide an apparent reason for one skilled in the art to combine the cited references to arrive at the method of amended claim 7, amended claim 7 is patentable over the combination of Phinney, et al., Visser, et al, Bogentoft, and The Merck Index.

Claims 8-9 and 11 depend directly or indirectly from claim 7. As such, claims 8-9 and 11 are patentable over the cited references for the same reasons as claim 7 set forth above, as well as for the additional elements they require.

CONCLUSION

In light of the foregoing, Applicants request withdrawal of the rejections of claims 1-11 and 30-32 and allowance of all pending claims. The Commissioner is hereby authorized to charge the fee for the Request for Continued Examination filed herewith and any additional government fees which may be required to Deposit Account No. 01-2384.

Respectfully Submitted,

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